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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/086,327	05/28/98	DURETTE	P 19965Y
			EXAMINER

HM22/1022

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EXAMINER	PAPER NUMBER
1654	11

DATE MAILED: 10/22/99

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 8/12/99

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 6-17, 20, 21 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
☐ Claim(s) \_\_\_\_\_ is/are allowed.  
☒ Claim(s) 6-17, 20, 21 is/are rejected.  
☐ Claim(s) \_\_\_\_\_ is/are objected to.  
☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.  
☐ The specification is objected to by the Examiner.  
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.  
☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892  
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  
☐ Interview Summary, PTO-413  
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948  
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Pursuant to the directives of paper No. 10 (filed 8/12/99), claims 1-5 and 18-19 have been cancelled. Claim 21 has been added. Claims 6-11, 13, 15 have been amended to reflect a change in claim dependence. Claims 6-17, 20, 21 are pending.

Applicants' arguments filed 8/12/99 have been considered and found persuasive in part. The §102 rejection over Voigt (*Pharmazie* 41, 233, 1986) is withdrawn herewith.

\*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-17, 20, 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification asserts that the claimed compounds are antagonists of VLA-4 or  $\alpha_4\beta_7$ . However, applicants have provided no evidence that this is the case. The specification also asserts that the compounds can be used to treat asthma, allergies, inflammation, MS, and other autoimmune diseases. However, even if it were shown that the compounds are in fact antagonists of VLA-4 or  $\alpha_4\beta_7$ , it would not necessarily follow therefrom that any disease can be successfully treated. Issues such as proper anatomical localization and

sufficient as well as selective receptor antagonism remain to be shown. Undue experimentation would be required of the skilled artisan to determine which of the compounds can be used to antagonize VLA-4 or  $\alpha_4\beta_7$ , or to treat a given disease.

\*

Claims 15 and 20 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is dependent on a cancelled claim (claim 5). Variables  $R^b$  and  $R^y$  are described as being defined in claim 5. The definition of variables  $R^b$  and  $R^y$  should be made clear.

Claim 20 is dependent on a cancelled claim (claim 5).

\*

Claims 6-9, 11, 12 and 21 are rejected under 35 U.S.C. §102(b) as being anticipated by El-Naggar (*Acta Pharm. Jugosl.* 35 15, 1985).

El-Naggar teaches each of the following peptides, wherein "Ar" is dibenzofuran:

Ar-SO<sub>2</sub>-Pro-Phe-OMe  
Ar-SO<sub>2</sub>-Pro-Tyr-OMe  
Ar-SO<sub>2</sub>-Pro-Ser-OMe  
Ar-SO<sub>2</sub>-Pro-Val-OMe

The claims encompass these compounds. Applicants' variable  $R^1$  can be Cy; Cy, in turn, can be "heterocyclyl" or "heteroaryl". The dibenzofuranyl group is both "heterocyclyl" and "heteroaryl".

Thus, the claims are anticipated.

\*

Claim 20 is rejected under 35 U.S.C. §103 as being unpatentable over El-Naggar (*Acta Pharm. Jugosl.* **35** 15, 1985).

The teachings of the reference are indicated above. The reference does not teach "pharmaceutical compositions". However, the pharmaceutical formulation specialist of ordinary skill is well acquainted with methods of preparing such, and would have have sufficient motivation to do so.

\*

Claim 20 is rejected under 35 U.S.C. §103 as being unpatentable over Voigt (*Pharmazie* **41**, 233, 1986).

As indicated previously, Voigt teaches compound 4 (page 233) which corresponds to one of applicants' compounds in which the substituent variables correspond as follows:

R1 = *beta*-naphthyl,  
B = C  
Z = C  
X = COOH  
R4 = hydrogen  
R5 = *para*-cyano-benzyl

Claim 20 is currently dependent on a cancelled claim; this rejection will be maintained until such time as it becomes clear what is encompassed by claim 20.

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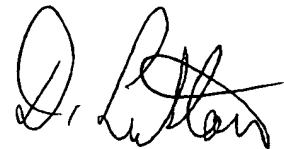
\*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton [phone number (703)308-3213].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



**DAVID LUKTON  
PATENT EXAMINER  
GROUP 1800**